MEDICAL DEVICE ANCHOR AND DELIVERY SYSTEM

BACKGROUND OF THE INVENTION

Recent advances in medical technology have resulted in the development of a variety of medical devices for permanent or temporary implantation in the human body. Effective positioning of such devices can prove to be a very difficult task, and maintaining an implanted device in a desired position for an extended period of time is often more difficult. This is particularly true if the implanted device is to remain only temporarily and is designed to facilitate subsequent removal.

A number of medical implant devices are designed to collapse for insertion within a catheter or other delivery unit and to expand to a predetermined shape when ejected after delivery. Many of these self expanding devices rely primarily upon the contact between the device and the wall of a body vessel or passageway to maintain the device in position after the delivery unit is removed. Unfortunately, changes in the configuration of the body vessel or passageway or variations in the flow of blood or other fluids there through can cause the medical implant to migrate and change position.

It is extremely important that a medical implant device be properly positioned and oriented, and that this position and orientation be maintained. Otherwise, effective performance of such therapeutic devices will not be achieved. It is often very difficult to move such a device into position with the desired orientation, and once this is achieved, it is critical that no further motion occur.

In an attempt to prevent migration of a medical implant device, rigid hooks are often formed on the device to engage the wall of a body vessel or passageway as the implant device expands into contact with the wall. After a few weeks, the endothelium layer grows over rigid hooks which will not easily bend under the influence of withdrawal pressure, and the medical implant device will be locked in place by the embedded hooks. This may be acceptable for a permanent implant, but rigid hooks are not a viable option if the medical implant device is to be removed after several weeks or months.

To facilitate removal of a previously implanted medical device by withdrawal of the anchoring hooks from an enveloping endothelium layer without risking substantial damage to the wall of a body vessel or passageway, the hooks have been formed to straighten when subjected to a withdrawal force greater than a maximum migration force. U.S. Patent Nos. 6,007,558 and 6,258,026 to Ravenscroft, et al show hooks which are formed to bend and straighten in response to a withdrawal force, while U.S. Patent Nos. 4,425,908 to Simon, 4,817,600 to Herms, et al, 5,108,418 to Lefebvre, 5,133,733 to Rasmussen, et al, 5,242,462 to El-Nounou, et al, 5,370,657 to Irie, 5,601,595 to Smith, 5,800,457 to Gelbfish, and 5,5853,420 to Chevillon, et al all disclose expandable medical implant devices; many with anchoring hooks.

Anchoring hooks, although effective in many instances, are subject to a number of disadvantages which can make it difficult to properly position and maintain the position of a medical implant device. In prior devices, the anchoring hooks are engaged due to the expansion of the device into contact with the wall of a body vessel or passageway, and if the device moves from a desired position during expansion and contact with the wall occurs, the device cannot be easily repositioned. The anchoring function of the hooks is not separable from the expansion of the device.

In cases where the operation of the hooks is tied to the expansion of a medical implant device, there can be instances where one or more of the hooks fails to properly pierce the wall of a body vessel or passageway causing the device to become off center. Sometimes movement of the device longitudinally will engage the errant hooks, but this movement can also alter the position of the device.

Finally, the configuration of a hook which curves in a single direction from a shaft to a pointed end can prove to be a disadvantage. When hooks are used to anchor a medical implant device within a blood vessel, it is important that the hook be oriented to curve in the direction of normal blood flow through the vessel as it engages the vessel wall. Thus when engaged, the hook will extend from the shaft toward the point substantially in the direction of the longitudinal axis of the blood vessel, and will effectively resist migration of the medical implant device in response to pressure thereon from blood flow in the normal direction through the blood vessel. However, there are conditions which can result in a backflow of blood in a blood vessel, and pressure on the device and the anchoring hooks resulting from such backflow can cause the hooks to back out and disengage from the vessel, thus changing the orientation of the device within the blood vessel and causing deleterious changes in the performance of the implant.

SUMMARY OF THE INVENTION

It is a primary object of the present invention to provide a novel and improved method for positioning and anchoring a medical implant device which includes positively propelling one or more anchors through a body wall subsequent to a medical implant device connected to the anchor reaching a desired position and coming to rest.

Another object of the present invention is to provide a novel and improved medical device anchor and delivery system wherein one or more anchors are positively propelled through a body wall. Once an anchor has passed through the wall, it expands outwardly from at least two opposed sides of an anchor shaft.

An additional object of the present invention is to provide a novel and improved medical device anchor designed to penetrate a body wall from a first side to a second side and to expand outwardly from at least two opposed sides of an anchor shaft after penetration.

Another object of the present invention is to provide a novel and improved medical device anchor designed to penetrate the wall of a body vessel from a first side to a second side and to expand outwardly from at least two opposed sides of an anchor shaft in a unique manner after penetration. The expanded anchor is designed to be loaded in compression against the second wall of the vessel in response to forces normal to the longitudinal axis of the vessel which are applied to a medical device attached to the anchor.

A further object of the present invention is to provide a novel and improved medical device anchor and delivery system wherein one or more anchors are positively propelled through a body wall subsequent to a medical implant device connected to the anchors reaching a desired position and coming to rest. The anchor delivery system facilitates removal and reinsertion of the anchors without requiring that the medical implant device connected thereto be compressed and/or removed.

Yet another object of the present invention is to provide a novel and improved anchor and anchor delivery system for a medical implant device to anchor the device in position within a blood vessel or other body passageway. Once the medical implant device has been positioned and expanded into contact with the wall of the blood vessel or body passageway, the anchor delivery system then positively propels one or more anchors through the vessel or passageway wall where the anchors expand outwardly on opposite sides of an anchor shaft. The anchor delivery system permits the anchors to be withdrawn and then reinserted through the wall without the necessity to collapse the medical implant device.

A further object of the present invention is to provide a novel and improved anchor and anchor delivery system for a medical implant device to anchor the device in position within a blood vessel or other body passageway while facilitating the subsequent withdrawal of the device. The anchor delivery system positively propels one or more anchors through the wall of a blood vessel or body passageway once the medical implant device has expanded into contact with the wall, and the anchors then expand outwardly from opposite sides of an anchor shaft. The anchors are formed to contract back toward the longitudinal axis of the anchor shaft in response to a predetermined force to permit withdrawal through the wall.

A still further object of the present invention is to provide a novel and improved anchor and anchor delivery system for a blood clot filter where the delivery system includes elongate, tubular filter legs which house the anchors. Once the filter legs are ejected from a catheter or delivery tube and expand into contact with the blood vessel wall, the anchor delivery system positively propels the anchors outwardly from the filter legs and through the blood vessel wall from a first side to a second side where the anchors expand outwardly on opposite sides of an anchor shaft against the second side of the wall. Each anchor is formed to contract back toward the longitudinal axis of its anchor shaft in response to a predetermined force to permit withdrawal through the wall, and this permits the anchors to be withdrawn back into the filter legs and then again propelled through the

blood vessel wall without collapsing the filter legs.

These and other objects of the present invention are achieved by providing an anchor delivery system which houses one or more uniquely configured anchors which are connected to a medical implant device. The anchors remain housed until after the medical implant device has come to rest in a desired position within a body, and then the anchors are positively propelled through a body wall from a first side to a second side where each anchor expands from a single shaft configuration outwardly on opposite sides of an anchor shaft. To propel the anchors, a drive shaft extends from an anchor support sleeve back to a triggering unit which, when activated, causes the drive shaft to move the anchor support sleeve in a direction to propel the anchors through the body wall. The triggering unit may be spring powered or solenoid powered.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a sectional view showing a blood clot filter with anchors formed in accordance with the present invention mounted within a catheter;

Figure 2 is a perspective view showing the anchor support hub and leg retention sleeve of Figure 1;

Figure 3 is a perspective view showing the locking sleeve for the leg retention sleeve of Figure 2;

Figure 4 is a sectional view showing the operating mechanism for the locking sleeve and anchor support hub of Figure 1;

Figure 5 is a perspective view showing a spring powered triggering unit at the proximal end of the catheter of Figure 1 for propelling the anchor support hub;

Figure 6 is a perspective view of the deployed blood clot filter of Figure 1;

Figure 7 is a perspective view of a deployed anchor for the blood clot filter of Figure 6;

Figure 8 is a perspective view of a second embodiment of a deployed anchor of the present invention;

Figure 9 is a perspective view of a third embodiment of a deployed anchor of the present invention; and

Figure 10 is a sectional view of a single anchor and anchor delivery system of the present invention.

DETAILED DESCRIPTION

Referring to Figures 1-2, a blood clot filter which includes anchors in accordance with the present invention is illustrated generally at 10.This filter, shown for illustration as a vena cava filter, is formed with a plurality of elongate legs12 which are secured to, and extend outwardly from a leg retention sleeve 14. The elongate legs are formed by small, open ended tubes each having a first open end 16 which opens at the leg retention sleeve. A plurality of long shafts 18 are attached at a distal end to an anchor support hub 20 which is spaced from the leg retention sleeve when the vena cava filter is collapsed within a catheter or delivery tube 22. Each shaft 18 extends from the anchor support hub 20 into the first open end 16 of a tubular leg 12 and through the leg to a distal end 24 at a point adjacent to a second open end 26 of the tubular leg. An anchor 28 is formed at the distal end of each shaft 18 in a manner to be described.

The elongate legs 12 and the long shafts 18 are formed of a material which will permit them to be compressed toward the longitudinal axis of the filter 10 for delivery by a catheter 22. Once the filter is ejected from the catheter, the legs 12 and the shafts 18 are designed to expand outwardly from the filter longitudinal axis as shown in Figure 6 to bring the legs into contact with the wall of a blood vessel. Although spring metal and suitable plastics can be used to form the legs 12 and/or the shafts 18, it is preferable to form the shafts 18 and in most cases the legs 12 of a suitable shape memory material. If a temperature responsive shape memory material such as nitinol is used, transition between the martensitic and austenitic states of the material can be achieved by temperature transitions relative to a transition temperature. In the martensitic state, the material softens, thereby permitting a filter formed thereof to be compressed and loaded into a catheter. If the transition temperature of the material is set at, or near to normal body temperature, then the filter legs will pass to the austenitic state when the filter is ejected from the catheter and expand to regain a memorized shape.

For delivery through the catheter 22, the leg retention sleeve 14 is locked to the anchor support hub 20 by a locking sleeve 30 which surrounds both the anchor support hub and the leg retention sleeve when in the locking position as shown in Figure 1. In the unlocked position, the locking sleeve is moved longitudinally back away from the leg retention sleeve as shown in Figure 3. Two spring arms 32 are connected at one end to a housing 34 behind the anchor support hub and extend outwardly over opposite sides of the leg retention sleeve. The free end of each of the spring arms is curved to form an arcuate latch member 36 which overlies and, in the locking position of Figure 1, engages a locking projection 38 formed on the leg retention sleeve. When the locking sleeve 30 moves toward the locking position over the leg retention sleeve 14, it forces the spring arms 32 and 34 together and the arcuate latch members engage the locking projections. As the locking sleeve reaches the full locking position of Figure 1, the arcuate latch members slide into slots 40 in the locking sleeve and the leg retention sleeve is positively locked to the anchor support hub. However, as the locking sleeve is moved longitudinally away from the leg retention sleeve, the arcuate configuration of the latch members 36 permits them to slip out of the slots 40, and as the locking sleeve moves further, the spring arms32 move

outwardly causing the arcuate latch members to disengage the locking projections 38.

The locking sleeve 30 is mounted for movement toward and away from a centering shaft 42 which extends from a distal end 44 adjacent to the vena cava filter 10 back to the entry end of the catheter 22. The distal end of the centering shaft is formed with a plurality of spaced lumens 46, each of which mounts one of a plurality of centering arms 48. The centering shaft moves these centering arms out of the catheter 22 behind the vena cava filter, and these centering arms then expand outwardly to engage the vessel wall and center the leading end of the filter. These centering arms can be formed of spring metal or plastic, but are preferably formed of shape memory material such as nitinol.

To control the positioning of the vena cava filter 10 and subsequent ejection of the anchors 28 from the second open ends of the legs 12, an elongate drive shaft 50 extends from the entry or proximal end 52 of the catheter 22 through the catheter to a releasable connection 54 with the anchor support hub 20.This releasable connection can be any suitable connection which facilitates release of the drive shaft from the anchor support hub by manipulation of the drive shaft at the proximal end of the catheter such as a threaded connector as shown, a hook and eye connector, engaging hook connectors, and known twist engagement and release connectors.This drive shaft passes through the centering shaft 42 and is both rotationally and longitudinally movable relative thereto.

As shown in Figure 4, the drive shaft passes through and is both rotationally and longitudinally movable relative to a locking sleeve operator 56 which passes through slots 58 and 60 in the housing 34. The locking sleeve operator is secured at 62 and 64 to the locking sleeve 30 and operates to move the locking sleeve away from the leg retention sleeve 14 as the locking sleeve operator moves away from the leg retention sleeve in the slots 58 and 60. The drive shaft operates to move the locking sleeve from the locked position by means of a stop 66 secured to the drive shaft and positioned to engage the locking sleeve operator.

When the catheter 22 reaches a desired position within a blood vessel, the vena cava filter 10 and centering arms 48 are exposed by either ejecting them from the catheter or drawing the catheter back from around them. Now the elongate legs 12 and centering arms 48 will expand outwardly into engagement with the vessel wall. However, the anchors 28 will remain enclosed within the elongate legs, and this permits the vena cava filter to be moved relative to the blood vessel after expansion of the elongate legs until an exact position is attained. If a substantial position change is required, the centering arms and vena cava filter can be drawn back into the catheter and subsequently redeployed in a new position.

With the vena cava filter in the desired position within a blood vessel and the elongate legs 12 engaging the vessel wall, the anchors 28 are now positively ejected out from the second open ends 26 of the elongate legs so as to penetrate through the vessel wall. To achieve this positive ejection of the anchors subsequent to engagement of the elongate legs with the vessel wall with sufficient force to result in penetration of the vessel wall, the

drive shaft 50 is connected to a triggering unit 68 at the proximal or entry end 70of the catheter 22. This triggering unit can be formed by a number of known units capable of imparting a longitudinal force to the drive shaft. An electrically powered solenoid unit can be used for this purpose as well as a number of spring powered units. In Figure 5, the triggering unit is formed by a conventional ballistic-type lancer of the type commonly used to cause a needle to puncture a patient's skin to provide a blood sample. Such lancers include a hollow body 72 which contains a plunger 74 capable of moving axially back and forth within the body. The plunger is surrounded by a coil spring 76 which becomes compressed when the plunger is pulled back and armed by an end knob 78. The armed plunger is held in place by a trigger 80 which is activated to release the plunger by a button 82. When the plunger is released, the coil spring 76 propels the plunger toward an opening 84 in a nose cap 86 attached to the hollow body. For normal use of the ballistic type lancer, a needle is secured to the end 88 of the plunger and is propelled by the released plunger out through the opening 84 and into the skin of a patient. In Figure 5, the drive shaft 50 is secured to the end 88 of the plunger, and when the armed plunger is released, the drive shaft is propelled longitudinally to drive the anchor support hub 20 toward the leg retention sleeve 14. This causes the long shafts 18 to move longitudinally through the elongate legs 12 to propel the anchors out and through the vessel wall. Figure 6 illustrates an expanded vena cava filter 10 with the anchors 28 in the configuration that they would assume after passing through the vessel wall. The structure and operation of these anchors will be subsequently described.

A significant advantage of the vena cava filter 10 is that it can be repositioned even after the anchors are in place without the necessity to withdraw the complete filter back into the catheter 22. So long as the elongate legs are in contact with the vessel wall, the anchors 28 can be withdrawn from the vessel wall and back into the elongate legs by causing the drive shaft 50 to move the anchor support hub 20 away from the leg retention sleeve 14. Now the vena cava filter can be repositioned, the plunger 74 of the triggering unit 68 can be rearmed, and the anchors can again be ejected to pierce the vessel wall.

Once the vena cava filter 10 is properly positioned and anchored within a blood vessel, the drive shaft 50 is disconnected from the anchor support hub 20 and is pulled away from the anchor support hub causing the stop 66 to engage and move the locking sleeve operator 56 away from the anchor support hub. This results in movement of the locking sleeve 30 away from the leg retention sleeve 14 so that the spring arms 32 spring outwardly and the latch members 36 disengage from the locking projections 38. Now the centering shaft 42, locking sleeve 30, drive shaft 50 and housing 34 may be drawn back through the catheter 22 leaving the vena cava filter in place within the blood vessel.

To subsequently remove a previously anchored vena cava filter, the drive shaft 50 or a similar shaft is connected to the releasable connection 54 and is used to move the anchor support hub 20 longitudinally away from the leg retention sleeve 14. This draws the anchors 28 out of the blood vessel wall. Continued withdrawal force from the shaft will now cause the entire vena cava filter to be drawn into a catheter or delivery tube for removal,

The anchors 28 are formed at the proximal ends of the long shafts 18, and within the elongate legs 12 the anchors assume the same configuration as the shafts with which they are integrally formed. The shafts conform in configuration to the internal configuration of the elongate legs so as to easily move longitudinally within the elongate legs, and usually the shafts will be cylindrical with a pointed end which forms the leading end of the anchor. An enlarged view of the anchor of Figure 6 is shown in Figure 7.

Referring to Figure 7, the tubular shaft 18 is split down the center at 90 to form the opposed arms 92 and 94 of the anchor. The inner surfaces 96 and 98 of each of the arms is flat while the remaining surface 100 of each arm is arcuate, so that when the inner surfaces of the arms are contacting, a straight tubular end section is formed on the end of each long shaft 18. The pointed end of each long shaft forms the pointed ends 102 and 104 on the arms 92 and 94 of the anchor.

The expanded shape memory configuration of the anchors 28 is shown in Figures 6 and 7. Each anchor with the inner surfaces 96 and 98 in contact is ejected from an elongate leg 12 in a straight configuration when the anchor support hub 20 is driven toward the leg retention sleeve 14. The pointed lead end of each anchor will pierce the wall of a blood vessel so that the entire anchor passes through the vessel wall, at which point the anchor expands to its shape memory configuration shown in Figure 7. Now the end 26 of the elongate leg engages the inner surface of the blood vessel wall while the pointed ends 102 and 104 of the arms 92 and 94 engage the outer surface of the blood vessel wall. It is important to note that portions of the expanded anchor, in this case the arms 92 and 94, extend outwardly on opposite sides of the shaft 18 so that forces in either direction in the plane of the anchor arms will not dislodge the anchor in the manner which can occur with a single hook which extends outwardly in only one direction from a support shaft. To provide additional protection from accidental dislodgement, the anchors 28 are oriented as shown in Figure 7 so that the opposed arms 92 and 94 of the anchor expand transversely to the longitudinal direction 106 of blood flow through the filter 10. Thus the forces created by direct or reverse blood flow cannot dislodge the anchor, but since the anchor arms are each formed from half of a shaft 18 of a very small diameter, a withdrawal force along the longitudinal axis of the shaft will permit the anchor arms to come together to facilitate anchor withdrawal from the vessel wall.

It is important to note that the anchor arms 92 and 94 curve outwardly and back toward the shaft 18 to engage the outside surface of the vessel wall. This causes the anchor to be loaded in compression against the vessel wall when forces normal to the longitudinal axis of the vessel are applied to a medical device attached to the anchor. This compression aspect greatly enhances the anchoring function provided by the anchor and facilitates the effective use of very small, fine anchor components.

The anchors 28 may take a number of forms so long as the anchor expands from a straight configuration from within an elongate leg 12 to a shape memory configuration where the anchor extends outwardly on at least two opposite sides of the shaft 18. In

Figure 8, the anchor 28 expands to a spiral cofiguration so as to extend completely around the shaft 18. Here the shaft is not split as shown in Figure 7, but instead the intact end of the shaft is used to form the spiral 108. In all cases, first end of the anchor to emerge from an elongate leg 12 is a straight section 110 bearing the anchor point, and this section passes through a blood vessel wall before following sections which will form curves emerge. Both the anchors of Figures 7 and 8 tend to flatten by spring action against the vessel wall after expanding.

To form the anchor 28 of Figure 9, the shaft 18 is flattened at the end and split at 90 to form two opposed , flat arms 112 and 114 which expand outwardly on opposite sides of the shaft. These arms emerge from the elongate leg 12 as a straight section which passes through the vessel wall and then splits and bends outwardly at 116 and 118 to form the arms. These arms lie against the outer surface of the vessel walland in a vena cava filter, are oriented transverse to the longitudinal direction of blood flow through the filter.

For some medical applications, a need has arisen for a single anchor to tether a device within a body vessel or to a body wall. An apparatus similar to that previously described with reference to the multiple anchor vena cava filter 10 can be employed to deploy the single anchor 120 of Figure 10. The single anchor 120 is formed at the distal end of an anchor shaft 122 mounted in an elongate tube 124, Both the shaft 122 and the tube 124 are formed of shape memory material as desribed relative to the elongate legs 12 and long shafts 18, but are normally much shorter in length than the elongate legs and shafts 18. A tube retention sleeve 126 retains the single tube 124 in the same manner that the leg retention sleeve14 operates to retain the elongate legs l2, and this tube retention sleeve is engaged by a locking sleeve (not shown) and spring arms 32 operative in the manner previously described. A drive shaft 50 is connected at the entry end of the catheter 22 to a triggering unit 68, and is also connected to a releasable connection 128 similar to the releasable connection 54. This releasable connection is firmed in a shaft support hub 130 normally spaced from the tube retention sleeve 126 which ss connected to the proximal end of the anchor shaft.

The drive shaft 50 is movable in a control shaft 132 similar to the centering shaft 42 which operates to move the shaft support hub and tube retention sleeve longitudinally to expel the tube 124 containing the anchor 120 from the catheter 22. The tube 124 will now assume a predetermined shape to position the anchor relative to a body wall which will receive the anchor. Now the triggering unit 68 can be operated to cause the drive shaft 50 to move the shaft support hub 130 toward the tube retention sleeve 126 to drive the anchor 120 through the body wall. The anchor 120 is formed of shape memory material and can take the form and operate in the manner of any of the anchors previously described. Once the anchor is delivered, the spring arms 32 can be operated to release the tube retention sleeve 126, and the drive shaft can be released from the releasable connection 128 so that the drive and control shafts, and in some cases the catheter, can be withdrawn. If the purpose of the anchor is to anchor the catheter in position, then a tether 134 is provided between the catheter and the anchor, and the catheter will not be